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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/645,814
Filing Date: August 21, 2003
Appellant(s): COUVILLON, LUCIEN A.

David Bonham
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 07 June 2007 appealing from the Office action mailed 11 August 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The provisional double patenting rejection of the claims over the copending Application No. 10/373,940 has been withdrawn because the copending claims have been amended to overcome the double patenting rejection.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,123,681	Brown,III	9-2000
2005/0137507	Shabty et al.	6-2005
6,249,076	Madden et al.	6-2001
2004/0230090	Hegde et al.	11-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Brown III in view of Shabty et al., Madden et al. and Hegde et al.

Brown teaches applicant's system for exerting a compressive force on an exterior treatment portion of a user's body to assist the return of blood to the heart from the extremities by compressing the veins and relying on the venous valves to favor one-way flow so that the heart need not do all the work of perfusion. The device includes a covering member for covering the treatment portion comprising an electroactive polymer (EAP) actuator operably connected to the covering for compressing the treatment portion of the user's body. Brown gives examples of the polymers that are useful in his invention however, Brown's invention is not restricted to any one of the given examples. Brown does not want to be limited to such details. Other obvious equivalent alternative polymers would have been an obvious modification.

Applicant's own disclosure admits that the details of the EAP are well known. Such details have already been provided by the prior art. The details of the electroactive polymer actuator are well known as admitted by applicant's disclosure in the paragraph beginning on the

bottom of page 5 and continuing to page 6. "Additional information regarding the construction of such actuators, their design considerations and the materials and components that may be deployed therein can be found, for example, in U.S. Pat. No. 6,249,076..." The noted prior art patent 6,249,076 is Madden which teaches the details of the electroactive polymer actuator including a counter electrode and an electrolyte-containing region.

Both Brown and applicant's invention are not limited to the details of the EAP. Such details are provided by the prior art such as Madden. As admitted by applicant, it would have been obvious to one of ordinary skill to modify Brown to use any conventional EAP such as that taught by Madden as further taught by applicant as an obvious equivalent alternative EAP for performing the same function. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

The Brown device is for applying compressive forces to parts of the body to stimulate blood flow. The Brown device is a stocking that is capable of being placed on a portion of the body and then having stimulus applied thereto to stimulate blood flow (column 1, lines 10-16). Brown teaches that prior art stocking merely constricts the musculature of the lower extremity but does not mimic the pulsatile milking action of the leg muscles upon the veins which enhance venous blood flow back to the heart (column 1, lines 54-58). "There is need to provide a sequential application of compressive forces for squeezing or constricting the muscles thereof to prevent stasis of blood with resultant thrombus formation in the leg veins and pulmonary emboli associated therewith" (column 2, lines 37-41). Clearly Brown's device is for sequential compressions of the extremities to help blood flow back to the heart in patients that have compromised circulatory systems.

The Shabty device is also for applying compressive forces to parts of the body to stimulate blood flow. The Shabty device is a wrap that is placed on a portion of the body in segments including the ankle, calf, thigh, and buttocks sections. Tissue compression is applied to each component sequentially (paragraph 13). Shabty also teaches the apparatus producing the tissue compression enhancing blood flow may also be applied uniquely on every other heart beat, every second beat, or every third beat, depending on which sequence produces the most augmentation (paragraph 14). The compressions are a timed, pressurized pulse of blood back toward the heart when the heart is normally resting between beats. Therefore the pressurized pulse of blood flow back toward the heart does not occur at the same time the heart is trying to product a pressurized pulse out toward the extremities i.e., "counterpulsation". Clearly Shabty already teaches the advantage of applying compressive forces on the treatment portion of the body and takes it a step further by synchronizing the compressive forces with the heartbeat to improve blood flow back toward the heart without opposing the hearts efforts.

Hegde is also cited to teach that using EAP in the form of a wrap for the treatment of enhancing blood flow back to the heart when synchronized with the heartbeat is not a foreign idea. Hedge teaches, "FIG. 62 illustrates a comparison of arterial pressure and a corresponding EKG readout when an embodiment of an EAP actuated vascular assist system is providing augmentation is in a counterpulsation manner" (paragraph 244, lines 6-10). "In order to actuate the EAP elements to provide counterpulsation the pump and pacing controller 415 calculates the Q-T interval for the heart rate and triggers at the appropriate moment based on the response time of the EAP actuated system being used" (paragraph 247, lines 4-9). Therefore Hegde is an additional reference that teaches it is well known to use an EAP device to provide a

counterpulsation apparatus for exerting a compressive force on a treatment portion of the user's body in synchrony with the heart beat of the user.

It would have been obvious to one of ordinary skill in the art to modify Brown and use the details of the EAP as taught by Madden as an obvious equivalent alternative means for doing the same thing as further suggested by applicant's admission and to use the device in synchrony with the heart beat as taught by Shabty to provide the added benefit of synchronizing compressions with the heart beat to augment blood circulation by timing it with the heart to help with the return of blood flow back to the heart. Hegde is also provided to teach that it is well known to use an EAP device in counterpulsation to augment blood flow back to the heart timed with the heart beat.

(10) Response to Argument

Applicant argues that the examiner's assertion that "Brown isn't restricted to any specific type of EAP actuator" is erroneous. It is not clear how applicant can disregard the teaching of Brown stating that the invention is a wrap in which "[t]he polymer strips used in the present invention are designed to react to a stimulus and constrict or contract, thereby causing the stocking to compress against the part of the body wrapped by the stocking" column 3, lines 64-67. "The polymers utilized in the present invention are those capable of contracting in response to a stimulus", "the stimulus is preferably an electrical charge", "[p]olymers useful in the present invention include, but are not limited to..." column 4, lines 26-42. Brown teaches a whole list of different types of polymers that are capable of doing the job. Brown teaches that he is "not limited to" any one specific type of ElectroActive Polymer. Therefore, someone looking for the details of design of a conventional EAP that can be used to apply forces in a mechanical

environment, one would look to other prior art devices that teach such details. Madden teaches actuators comprising an electroactive polymer member, a counter electrode and an electrolyte containing region disposed between the electroactive polymer member and the counter electrode to produce a force per unit area of at least 10 MPa (see abstract). Brown already teaches the overall structure has to be a sheet of material for wrapping the outside portion of the body's extremities. Madden teaches a sheet of material that can be used to apply forces to unspecified mechanical devices. Therefore, it would appear to be obvious to modify Brown to use the details of the EAP structure as taught by Madden for the EAP wrap of Brown to teach the details of the electroactive polymer in a mechanical design. At least such details would be an obvious equivalent alternative to the electroactive polymer of Brown in order to produce the same expected results

Applicant also argues that the examiner's assertion that "any conventional actuator would work" is an error of law. The examiner is merely pointing out that Brown is not restricted to any specific EAP and suggests many different types. Therefore one of ordinary skill in the art would search the prior art to see what would work best for their situation. Therefore the examiner is coming to the conclusion that any conventional EAP actuator would work as long as it provided the desired characteristics. Searching other teachings of EAP such as Madden one would find that Madden found an arrangement that worked best for mechanical devices. Madden exemplifies a conventional EAP structure that would work for mechanical environments.

Just as applicant's specification states in the paragraph spanning pages 5 and 6 that "[a]dditional information regarding the construction of such actuators, their design considerations and the materials and components that may be deployed therein can be found" in

a couple of different sources including Madden et al. This suggests that the details of the design, materials and components of the EAP that may be deployed in the present invention can be found in a couple of different prior art sources. Therefore applicant is not limited to any one specific design, materials and components as long as it has the basic characteristics claimed. The examiner is not using hindsight to make the combination, the examiner is merely pointing out that the specific design of the EAP is not critical to the device since applicant can use a plurality of different types of devices. The prior art already teaches the arrangement of the electroactive polymer, counter electrode and electrolyte claimed. It would appear that the combination of familiar elements according to known methods is likely to be obvious when it does not more that yield predictable results. Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. 103(a). Ex Parte Smith, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007) (citing KSR v. Teleflex, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a).

Regarding applicant's arguments on Shabty, the applicant states Brown is not directed to counterpulsation therapy. Rather, Brown is directed to embolism prevention. While this is true they both are directed at the art of improving blood circulation. The reason patients have

embolisms is because of poor circulation. Brown teaches "[t]he present invention relates generally to a system and method for applying compressive forces to parts of the body to stimulate blood flow" column 1, lines 10-12. "Accordingly, there is need to provide a sequential application of compressive forces for squeezing or constricting the muscles thereof to prevent stasis of blood" column 2, lines 36-38. The power source is programmed "to send impulses to the most distal segment first, then as this cycle of compression is waning, start compression of the next, more proximal segment. This occurs until the sequence has completed at the most proximal segment" column 4, lines 61-67. Shabty teaches the same method of constricting the limb from distal to proximal. "The inflatable cuffs are inflated in a sequence to enhance blood flow in a generally distal-to-proximal direction. The timing of the inflation of the cuffs is synchronized with portions of the IKG signal and plethysmographic wave of the patient to achieve the desire therapeutic effect" paragraph 24. Shabty additionally teaches the advantage of applying the synchronized compressions to be in synchrony with the heart beat of the user as claimed. Again, there appears to be no unobviousness to the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

Regarding Hegde, the examiner is not citing Hegde to teach implanting the EAP inside the body. Hegde is cited to teach that it is conventional to use EAP wraps around body portions for exerting compressive forces on the treatment portion of the user's body in synchrony with the heart beat of the user. It is not foreign to use EAP wraps with a system that times the compressions to be in synchronous with the heart beat.

Claim 10

Applicant states the examiner has not pointed out how the additional introduction of the feedback component is obvious in view of the prior art. The examiner may not have specifically pointed out how the prior art teaches these limitations because these limitations are self evident in the prior art. Shabty is cited to teach the convention of providing a system using the patient's EKG signal and plethysmographic wave to time the sequential compression with the patient's heart. The limitations of claims 10-14 are merely reciting the conventional elements required in order to use the EKG system of Shabty to time the sequence of compression therapy. Shabty teaches "[I]n the preferred embodiment, the counterpulsation therapy is carried out by timing the inflation and deflation of the treatment cuffs with certain characteristics of the patient's EKG signal and the plethysmographic blood pressure wave. Therefore, a conventional EKG 100 and a conventional pulse oximetry measurement system 102 must be appropriately set up so that the necessary signals can be obtained and communicated to the computer 10" paragraph 52. Clearly Shabty teaches the conventional EKG would have a sensor to sense the heartbeat so that the computer can obtain the appropriate signal in order to then provide a signal to provide the synchronized pressurization. This sensor that produces the heartbeat signal is a feedback component that senses the feedback characteristic which is the heartbeat and the computer then provides a feedback signal that is indicative of the sensed feedback characteristic in order to operate the compression therapy. Applicant is merely claiming the basic requirements of the EKG system that senses a metabolic characteristic for providing the feedback signal to the computer in order to time the compressions during the relaxation portion of the QRS wave.

Claim 11

All claim 11 is reciting is that a controller is configured to provide the drive signal based on the feedback signal. As noted above the computer obtains the metabolic signals in order to control the sequential compressions. Shabty already teaches this feature.

Claim 12

Claim 12 is reciting is the system has to include a metabolic sensor sensing a metabolic characteristic providing the feedback signal. That is the above noted EKG sensor that detects the heartbeat of the patient. The heartbeat sensor of the EKG system is the metabolic sensor sensing the metabolic characteristic. Shabty also teaches a plethysmographic blood pressure sensor. This is an additional metabolic sensor sensing a metabolic characteristic.

Claim 13

Claim 13 is reciting a blood flow sensor. The above noted EKG signal is based on the QRS wave of the heart which is a blood flow sensor because it detects the heartbeat which is when blood is flowing through the heart and surrounding blood vessels.

Claim 14

Claim 14 merely recites the feedback component comprises a blood pressure sensor. The above noted plethysmographic blood pressure wave sensor is a blood pressure sensor.

Claim 28

Applicant states the examiner has not pointed out how the additional introduction of sensing a biological characteristic indicative of an efficaciousness of the counterpulsation pressure and providing a biological sensor signal indicative of the sensed characteristic. The computer of Shabty includes a patient database that automatically updated to include information including heart rate, pulse oximetry readings. With the computer recording patient biological

characteristics comparing the data history of the patient would be indicative of the efficaciousness of the counterpulsation pressure as claimed.

Claim 29

Applicant states that the examiner has not pointed out how the additional introduction of actuating the EAP actuators based on the biological sensor signal. This has already been explained when referring to the EKG system that controls the EAP based on the heartbeat. Such comprehends claim 29.

Regarding the double patenting rejection, as noted above the double patenting rejection has been withdrawn.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Danton DeMille

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